

Docket No. 281387US0PCT



**MAIL STOP PCT**

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Fabrizio SAMARITANI, et al.

SERIAL NO: 10/561,529

GAU:

FILED: December 20, 2005

EXAMINER:

FOR: FREEZE-DRIED FSH/LH FORMULATIONS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☒ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 281387US0PCT		SERIAL NO. 10/561,529	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Fabrizio SAMARITANI, et al.			
				FILING DATE December 20, 2005		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	5 384 132	01/24/95	DE MEERE et al.			
	AB	5 162 306	11/10/92	DONALDSON			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	AC	0 853 945	07/22/98	EP	NO		
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AD	BURGUES et al. "Subcutaneous self-administration of highly purified follicle stimulating hormone and human chorionic gonadotrophin for the treatment of male hypogonadotropic hypogonadism", Human Reproduction, vol. 12, no. 5, pages 980-986 1997					
	AE	SHOME et al. "A Reevaluation of the Amino Acid Sequence of Human Follicotropin beta-Subunit", Journal of Protein Chemistry, vol. 7, no. 4, pages 325-339 1988					
	AF	KEUTMANN et al. "Structure of Human Luteinizing Hormone Beta Subunit: Evidence for a Related Carboxyl-Terminal Sequence Among Certain Peptide Hormones", Biochemical and Biophysical Research Communications, vol. 90, no. 3, pages 842-848 1979					
	AG	TALMADGE et al. "Evolution of the genes for the beta subunits of human chorionic gonadotropin and luteinizing hormone", Nature, vol. 307, pages 37-40 1984					
	AH	FIDDES et al. "Structure, Expression, and Evolution of the Genes for the Human Glycoprotein Hormones", Recent Progress in Hormone Research, vol. 40, pages 43-78 1984					
	AI	REICHERT et al. "Dissociation of Human Follicle-stimulating Hormone", Journal of Biological Chemistry, vol. 250, no. 8, pages 3034-3040 1975					
	AJ	KLEIN et al. "Pharmacokinetics and pharmacodynamics of single-chain recombinant human follicle-stimulating hormone containing the human chorionic gonadotropin carboxyterminal peptide in the rhesus monkey", Fertility and Sterility, vol. 77, no. 6, pages 1248-1255 2002					
	AK	FIDDES et al. "The Gene Encoding the Common Alpha Subunit of the Four Human Glycoprotein Hormones", Journal of Molecular and Applied Genetics, vol. 1, pages 3-18 1981					
	AL	MAURER et al. "Isolation and Nucleotide Sequence Analysis of a Cloned cDNA Encoding the beta-Subunit of Bovine Follicle-Stimulating Hormone", DNA, vol. 5, no. 5, pages 363-369 1986					
	AM	WATKINS et al. "DNA Sequence and Regional Assignment of the Human Follicle-Stimulating Hormone beta-Subunit Gene to the Short Arm of Human Chromosome 11", DNA, vol. 6, no. 3, pages 205-212 1987					
	AN	HIRAI et al. "The gene for the beta subunit of porcine FSH: absence of consensus oestrogen-responsive element and presence of retroposons", Journal of Molecular Endocrinology, vol. 5, pages 147-158 1990					
	AO	MAURER. "Molecular Cloning and Nucleotide Sequence Analysis of Complementary Deoxyribonucleic Acid for the beta-Subunit of Rat Follicle Stimulating Hormone", Molecular Endocrinology, vol. 1, pages 717-723 1987					
	AP	GUZMAN et al. "The Gene Encoding Ovine Follicle-Stimulating Hormone beta: Isolation, Characterization, and Comparison to a Related Ovine Genomic Sequence", DNA and Cell Biology, vol. 10, no. 8, pages 593-601 1991					
	AQ	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes. II. Structure of the luteinizing hormone beta-subunit-encoding genes", Gene, vol. 166, pages 335-336 1995				<input checked="" type="checkbox"/> Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							



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				FILING DATE December 20, 2005		GROUP	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes, I. Structure of the follicle-stimulating hormone beta-subunit-encoding gene", Gene, vol. 166, pages 333-334 1995					
	AS	STEELMAN et al. "Assay of the Follicle Stimulating Hormone Based on the Augmentation with Human Chorionic Gonadotropin", Endocrinology, vol. 53, pages 604-616 1953					
	AT	VAN HELL et al. "Effects of Human Menopausal Gonadotrophin Preparations in Different Bioassay Methods", Acta Endocrinologica, vol. 47, pages 409-418 1964					
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Examiner					Date Considered		
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U.S. PCT Application Serial No: 10/561,529

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Fabrizio SAMARITANI, et al.

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### STATEMENT OF RELEVANCY

- 1) References AA-AC have been cited in the International Search Report. A copy of these references is being submitted herewith.
- 2) References            have been cited in the corresponding            Search Report. A copy of these references is being submitted herewith.
- 3) References AD-AT are discussed in the specification. A copy of these references is being submitted herewith.
- 4) References            are additional prior art known to Applicant. A copy of these references is being submitted herewith.



Docket No.: 281387US0PCT

Serial No.: 10/561,529

Inventor: Fabrizio SAMARITANI, et al.

LIST OF RELATED CASES CITED BY  
APPLICANT UNDER 37 CFR 1.56

Filing Date: December 20, 2005

Group:

**LIST OF RELATED CASES**

<u>Examiner Initial</u>	<u>Docket No.</u>	<u>Serial or Patent Number</u>	<u>Filing or Issue Date</u>	<u>Patent App. Publication No.</u>	<u>Inventor or Applicant</u>
	281387US0PCT*	10/561,529	12/20/05		SAMARITANI, et al.
	278292US0PCT	10/551,840	10/03/05		SAMARITANI, et al.

Examiner

Date Considered

\*Present Application; listed for information  
NFO/amr/hah